DEPARTMENT OF HEALTH AND HUMAN SERVICES

30051

Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

December 19, 2001

VIA FEDERAL EXPRESS

Warning Letter No. 02-NSV-07

FACILITY ID# 187476

Roger Struber, Executive Director
The Medical Group
1734 Madison Avenue
Memphis, TN 38104

Dear Mr. Struber:

Your facility was inspected on December 7, 2001, by a representative of the State of Tennessee on contract to the U.S. Food and Drug Administration (FDA). This inspection revealed your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, *Code of Federal Regulations* (CFR), Part 900.12, as follows:

Level 1

- Failed to produce documents verifying that the interpreting physician, [redacted], met the initial requirement of holding a valid state license to practice medicine.

- Failed to produce documents verifying the interpreting physician, [redacted], met the initial requirement of being certified in the appropriate specialty by an FDA-approved board or having two months of initial training in the interpretation of mammograms prior to April 28, 1999.

- Failed to produce documents verifying the interpreting physician, [redacted], met the initial requirement of being certified in the appropriate specialty by an FDA-approved board or having two months of initial training in the interpretation of mammograms prior to April 28, 1999.

- Failed to produce documents verifying the interpreting physician, [redacted], met the initial requirement of being certified in the appropriate specialty by an FDA-approved board or having two months of initial training in the interpretation of mammograms prior to April 28, 1999.

- Failed to produce documents verifying the interpreting physician, [redacted], met the initial requirement of holding a valid state license to practice medicine.

- The system to communicate results is not adequate for the site The Medical Group because:

  - There is no system in place to provide timely lay summaries; and,
  - There is no system in place to communicate serious or highly suggestive cases as soon as possible (ASAP).

Level 2 (repeat noncompliances)

- Failed to produce documents verifying the interpreting physician, [redacted]., met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.

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- Failed to produce documents verifying the interpreting physician, [redacted]., met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.

- Failed to produce documents verifying the interpreting physician, [redacted], met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.

Level 2

- The measured fog density is equal to 0.1 for darkroom one at the site The Medical Group.

- The facility has not specified adequate procedures to be followed for infection control or did not follow them when required at the site The Medical Group.

- The facility has not specified adequate written procedures for collecting and resolving consumer complaints or did not follow them when required at the site The Medical Group.

- Failed to produce documents verifying the interpreting physician, [redacted], (0 CME's in 36 months) met the continuing education requirement of having taught or completed at least 15 category one continuing medical education units in mammography in 36 months.

- Failed to produce documents verifying the interpreting physician, [redacted], met the initial experience requirement of having interpreted or multi-read 240 mammograms in 6 months.

- Failed to produce documents verifying the interpreting physician, [redacted], met the initial experience requirement of having interpreted or multi-read 240 mammograms in 6 months.

- Failed to produce documents verifying the interpreting physician, [redacted], met the initial requirement of having 40 hours of medical education in mammography prior to April 28, 2001.

- Failed to produce documents verifying the interpreting physician, [redacted], met the initial requirement of having 40 hours of medical education in mammography prior to April 28, 2001.

- Failed to produce documents verifying the interpreting physician, [redacted], met the initial experience requirement of having interpreted or multi-read 240 mammograms in 6 months.

- Failed to produce documents verifying the interpreting physician, [redacted], met the initial requirement of having 40 hours of medical education in mammography prior to April 28, 2001.

- Medical audit and outcome analysis was not done separately for each individual at the site The Medical Group.

- There is no designated audit (reviewing) interpreting physician for the site The Medical Group.

Level 3 (repeat noncompliance)

- The required personnel qualification documents were not available during the inspection.

These specific deficiencies appeared on the Post Inspection Report, which was given to your facility by the state inspector at the close of your inspection, along with instructions on how to respond to these findings. These deficiencies may be symptomatic of serious problems that could compromise the quality of mammography at your facility and potentially overexpose both patients and employees involved with mammography.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies as identified and to promptly initiate permanent corrective action.

If you fail to properly address these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- Impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to comply with, the Standards;

- Suspend or revoke a facility's FDA certificate for failure to comply with the Standards; and/or,

- Seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of any similar violations.

If your facility is unable to complete these corrective actions within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125, with a copy to the State of Tennessee. Should you have questions regarding this letter or MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,

Carl E. Draper

Carl E. Draper
District Director
New Orleans District

CED:KRS:krs:krz

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